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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,199

10/15/2003

Paul Budworth

1392/11

6710

25297 7590 12/10/2008  
JENKINS, WILSON, TAYLOR & HUNT, P. A.  
Suite 1200 UNIVERSITY TOWER  
3100 TOWER BLVD.,  
DURHAM, NC 27707

EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/686,199	<b>Applicant(s)</b> BUDWORTH ET AL.	
	<b>Examiner</b> MICHELE K. JOIKE	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10, 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed August 18, 2008. Amendments were made to claims 1 and 9. Claims 4 and 11 are canceled. Claims 1-3, 5-10 and 12-19 are pending, claims 1-3, 5-10 and 12-17 are under consideration.

Any rejection of record in the previous Office Action, mailed April 17, 2008 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

#### ***Response to Arguments Concerning Claim Rejections –35 USC §103(a)***

Applicants' arguments filed on August 18, 2008 have been fully considered. The following grounds of traversal are presented:

Applicants' argue that claims 1 and 9 are methods directed to obtaining binding partners, and claim 16 is a method directed to screening for binding partners. Cronan supplies the binding partners, therefore they are already known. Therefore, Cronan does not support the instant rejection.

Furthermore, the binding partner is for the protein of interest, and not the affinity tag. In Cronan, the binding partner is disclosed to be an antibody that binds to the fusion protein via the post-translational modification sequence, as opposed to the claims which require binding to the protein of interest. Also, the post-translational modification

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sequence/affinity tag is to permit the fusion protein to be identified or isolated by means of the post-translational modification. The post-translational modifications are chosen beforehand to coincide with the known reagents.

Applicants also argue that one of ordinary skill in the art would not look to Rigaut to provide an affinity tag because Cronan already included one. If the skilled artisan replaced the biotination sequence with an affinity tag from Rigaut, the resulting construct would no longer encode a post-translational modification sequence.

Lastly, there is no basis for employing both a post-translational sequence, and a further affinity purification sequence.

Applicants' arguments have not been found persuasive for the following reasons.

The Examiner disagrees that the Cronan does not teach a method directed to obtaining binding partners. The word "obtaining" is broader than screening and does not exclude known partners. The Examiner is interpreting "obtaining" to have a similar meaning as providing. There is no language in the specification to indicate that "obtain" is equivalent to "screen." As for screening for binding partners, the Examiner was citing Rigaut, not Cronan, to teach this limitation, as explained in the prior office action. Rigaut, not Cronan, was also used to teach that the method is for identifying binding partners of the protein of interest. Although Cronan does teach an antibody as a binding partner, it also envisions other compounds that bind to the fusion protein. It does not state specifically that the binding partner is binding to the protein of interest, but again, that is what Rigaut teaches. Furthermore, in response to applicant's

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arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

There is no need to replace the biotination sequence with the tag from Rigaut. Rigaut teaches using one or two affinity tags. Since Cronan teaches that the biotination sequence can also act as a tag, there would be no need to replace it, if not desired.

#### ***Allowable Subject Matter***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike  
Examiner  
Art Unit 1636

/David Guzo/  
Primary Examiner  
Art Unit 1636